

115TH CONGRESS  
1ST SESSION

# H. R. 2430

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2017

Mr. WALDEN (for himself, Mr. PALLONE, Mr. BURGESS, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act to revise and extend the user-fee programs for prescription drugs, medical devices, generic drugs, and biosimilar biological products, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “FDA Reauthorization  
5 Act of 2017”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

#### TITLE I—FEES RELATING TO DRUGS

- Sec. 101. Short title; finding.
- Sec. 102. Authority to assess and use drug fees.
- Sec. 103. Reauthorization; reporting requirements.
- Sec. 104. Sunset dates.
- Sec. 105. Effective date.
- Sec. 106. Savings clause.

#### TITLE II—FEES RELATING TO DEVICES

- Sec. 201. Short title; findings.
- Sec. 202. Definitions.
- Sec. 203. Authority to assess and use device fees.
- Sec. 204. Reauthorization; reporting requirements.
- Sec. 205. Conformity assessment pilot program.
- Sec. 206. Reauthorization of review.
- Sec. 207. Electronic format for submissions.
- Sec. 208. Savings clause.
- Sec. 209. Effective date.
- Sec. 210. Sunset clause.

#### TITLE III—FEES RELATING TO GENERIC DRUGS

- Sec. 301. Short title; finding.
- Sec. 302. Definitions.
- Sec. 303. Authority to assess and use human generic drug fees.
- Sec. 304. Reauthorization; reporting requirements.
- Sec. 305. Sunset dates.
- Sec. 306. Effective date.
- Sec. 307. Savings clause.

#### TITLE IV—FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 401. Short title; finding.
- Sec. 402. Definitions.
- Sec. 403. Authority to assess and use biosimilar fees.
- Sec. 404. Reauthorization; reporting requirements.
- Sec. 405. Sunset dates.
- Sec. 406. Effective date.
- Sec. 407. Savings clause.

#### TITLE V—REAUTHORIZATION OF OTHER PROGRAMS

- Sec. 501. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.
- Sec. 502. Reauthorization of pediatric humanitarian device exceptions.
- Sec. 503. Reauthorization of the critical path public-private partnerships.
- Sec. 504. Reauthorization of pediatric device consortia.
- Sec. 505. Reauthorization of orphan grants program.
- Sec. 506. Reauthorization of inspection program.
- Sec. 507. Reauthorization of pediatric study of drugs.

## TITLE VI—ADDITIONAL PROVISIONS

Sec. 601. Technical corrections.

1       **TITLE I—FEES RELATING TO**  
2                               **DRUGS**

3       **SEC. 101. SHORT TITLE; FINDING.**

4           (a) SHORT TITLE.—This title may be cited as the  
5       “Prescription Drug User Fee Amendments of 2017”.

6           (b) FINDING.—The Congress finds that the fees au-  
7       thorized by the amendments made in this title will be dedi-  
8       cated toward expediting the drug development process and  
9       the process for the review of human drug applications, in-  
10      cluding postmarket drug safety activities, as set forth in  
11      the goals identified for purposes of part 2 of subchapter  
12      C of chapter VII of the Federal Food, Drug, and Cosmetic  
13      Act, in the letters from the Secretary of Health and  
14      Human Services to the Chairman of the Committee on  
15      Health, Education, Labor, and Pensions of the Senate and  
16      the Chairman of the Committee on Energy and Commerce  
17      of the House of Representatives, as set forth in the Con-  
18      gressional Record.

19       **SEC. 102. AUTHORITY TO ASSESS AND USE DRUG FEES.**

20           (a) TYPES OF FEES.—

21               (1) IN GENERAL.—Section 736(a) of the Fed-  
22       eral Food, Drug, and Cosmetic Act (21 U.S.C.  
23       379h(a)) is amended—

1 (A) in the matter preceding paragraph (1),  
2 by striking “fiscal year 2013” and inserting  
3 “fiscal year 2018”;

4 (B) in the heading of paragraph (1), by  
5 striking “AND SUPPLEMENT”;

6 (C) in paragraph (1), by striking “or a  
7 supplement” and “or supplement” each place  
8 either appears;

9 (D) in paragraph (1)(A)—

10 (i) in clause (i), by striking “(c)(4)”  
11 and inserting “(c)(5)”; and

12 (ii) in clause (ii), by striking “A fee  
13 established” and all that follows through  
14 “are required.” and inserting the following:  
15 “A fee established under subsection (c)(5)  
16 for a human drug application for which  
17 clinical data (other than bioavailability or  
18 bioequivalence studies) with respect to  
19 safety or effectiveness are not required for  
20 approval.”;

21 (E) in the heading of paragraph (1)(C), by  
22 striking “OR SUPPLEMENT”;

23 (F) in paragraph (1)(F)—

24 (i) in the heading, by striking “OR IN-  
25 DICATION”; and

1 (ii) by striking the second sentence;

2 (G) by striking paragraph (2) (relating to  
3 a prescription drug establishment fee);

4 (H) by redesignating paragraph (3) as  
5 paragraph (2);

6 (I) in the heading of paragraph (2), as so  
7 redesignated, by striking “PRESCRIPTION DRUG  
8 PRODUCT FEE” and inserting “PRESCRIPTION  
9 DRUG PROGRAM FEE”;

10 (J) in subparagraph (A) of such paragraph  
11 (2), by amending the first sentence to read as  
12 follows: “Except as provided in subparagraphs  
13 (B) and (C), each person who is named as the  
14 applicant in a human drug application, and  
15 who, after September 1, 1992, had pending be-  
16 fore the Secretary a human drug application or  
17 supplement, shall pay the annual prescription  
18 drug program fee established for a fiscal year  
19 under subsection (c)(5) for each prescription  
20 drug product that is identified in such a human  
21 drug application approved as of October 1 of  
22 such fiscal year.”;

23 (K) in subparagraph (B) of such para-  
24 graph (2)—

1 (i) in the heading of subparagraph  
2 (B), by inserting after “EXCEPTION” the  
3 following: “FOR CERTAIN PRESCRIPTION  
4 DRUG PRODUCTS”; and

5 (ii) by striking “A prescription drug  
6 product shall not be assessed a fee” and  
7 inserting “A prescription drug program fee  
8 shall not be assessed for a prescription  
9 drug product”; and

10 (L) by adding at the end of such para-  
11 graph (2) the following:

12 “(C) LIMITATION.—A person who is  
13 named as the applicant in an approved human  
14 drug application shall not be assessed more  
15 than 5 prescription drug program fees for a fis-  
16 cal year for prescription drug products identi-  
17 fied in such approved human drug applica-  
18 tion.”.

19 (2) CONFORMING AMENDMENT.—Subparagraph  
20 (C) of section 740(a)(3) of the Federal Food, Drug,  
21 and Cosmetic Act (21 U.S.C. 379j–12(a)(3)) is  
22 amended to read as follows:

23 “(C) LIMITATION.—An establishment shall  
24 be assessed only one fee per fiscal year under  
25 this section.”.

1 (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-  
2 tion 736 of the Federal Food, Drug, and Cosmetic Act  
3 (21 U.S.C. 379h) is amended to read as follows:

4 “(b) FEE REVENUE AMOUNTS.—

5 “(1) IN GENERAL.—For each of the fiscal years  
6 2018 through 2022, fees under subsection (a) shall,  
7 except as provided in subsections (c), (d), (f), and  
8 (g), be established to generate a total revenue  
9 amount under such subsection that is equal to the  
10 sum of—

11 “(A) the annual base revenue for the fiscal  
12 year (as determined under paragraph (3));

13 “(B) the dollar amount equal to the infla-  
14 tion adjustment for the fiscal year (as deter-  
15 mined under subsection (c)(1));

16 “(C) the dollar amount equal to the capac-  
17 ity planning adjustment for the fiscal year (as  
18 determined under subsection (c)(2));

19 “(D) the dollar amount equal to the oper-  
20 ating reserve adjustment for the fiscal year, if  
21 applicable (as determined under subsection  
22 (c)(3));

23 “(E) the dollar amount equal to the addi-  
24 tional direct cost adjustment for the fiscal year  
25 (as determined under subsection (c)(4)); and

1 “(F) additional dollar amounts for each  
2 fiscal year as follows:

3 “(i) \$20,077,793 for fiscal year 2018;

4 “(ii) \$21,317,472 for fiscal year 2019;

5 “(iii) \$16,953,329 for fiscal year  
6 2020;

7 “(iv) \$5,426,896 for fiscal year 2021;

8 and

9 “(v) \$2,769,609 for fiscal year 2022.

10 “(2) TYPES OF FEES.—Of the total revenue  
11 amount determined for a fiscal year under para-  
12 graph (1)—

13 “(A) 20 percent shall be derived from  
14 human drug application fees under subsection  
15 (a)(1); and

16 “(B) 80 percent shall be derived from pre-  
17 scription drug program fees under subsection  
18 (a)(2).

19 “(3) ANNUAL BASE REVENUE.—For purposes  
20 of paragraph (1), the dollar amount of the annual  
21 base revenue for a fiscal year shall be—

22 “(A) for fiscal year 2018, \$878,590,000;  
23 and

24 “(B) for fiscal years 2019 through 2022,  
25 the dollar amount of the total revenue amount



1 established under paragraph (1) for the pre-  
2 vious fiscal year, not including any adjustments  
3 made under subsection (c)(3) or (c)(4).”.

4 (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Sub-  
5 section (c) of section 736 of the Federal Food, Drug, and  
6 Cosmetic Act (21 U.S.C. 379h) is amended to read as fol-  
7 lows:

8 “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

9 “(1) INFLATION ADJUSTMENT.—

10 “(A) IN GENERAL.—For purposes of sub-  
11 section (b)(1)(B), the dollar amount of the in-  
12 flation adjustment to the annual base revenue  
13 for each fiscal year shall be equal to the prod-  
14 uct of—

15 “(i) such annual base revenue for the  
16 fiscal year under subsection (b)(1)(A); and

17 “(ii) the inflation adjustment percent-  
18 age under subparagraph (B).

19 “(B) INFLATION ADJUSTMENT PERCENT-  
20 AGE.—The inflation adjustment percentage  
21 under this subparagraph for a fiscal year is  
22 equal to the sum of—

23 “(i) the average annual percent  
24 change in the cost, per full-time equivalent  
25 position of the Food and Drug Administra-

tion, of all personnel compensation and  
benefits paid with respect to such positions  
for the first 3 years of the preceding 4 fis-  
cal years, multiplied by the proportion of  
personnel compensation and benefits costs  
to total costs of the process for the review  
of human drug applications (as defined in  
section 735(6)) for the first 3 years of the  
preceding 4 fiscal years; and

“(ii) the average annual percent  
change that occurred in the Consumer  
Price Index for urban consumers (Wash-  
ington-Baltimore, DC-MD-VA-WV; Not  
Seasonally Adjusted; All items; Annual  
Index) for the first 3 years of the pre-  
ceding 4 years of available data multiplied  
by the proportion of all costs other than  
personnel compensation and benefits costs  
to total costs of the process for the review  
of human drug applications (as defined in  
section 735(6)) for the first 3 years of the  
preceding 4 fiscal years.

“(2) CAPACITY PLANNING ADJUSTMENT.—

“(A) IN GENERAL.—For each fiscal year,  
after the annual base revenue established in

1 subsection (b)(1)(A) is adjusted for inflation in  
2 accordance with paragraph (1), such revenue  
3 shall be adjusted further for such fiscal year, in  
4 accordance with this paragraph, to reflect  
5 changes in the resource capacity needs of the  
6 Secretary for the process for the review of  
7 human drug applications.

8 “(B) INTERIM METHODOLOGY.—

9 “(i) IN GENERAL.—Until the capacity  
10 planning methodology described in sub-  
11 paragraph (C) is effective, the adjustment  
12 under this paragraph for a fiscal year shall  
13 be based on the product of—

14 “(I) the annual base revenue for  
15 such year, as adjusted for inflation  
16 under paragraph (1); and

17 “(II) the adjustment percentage  
18 under clause (ii).

19 “(ii) ADJUSTMENT PERCENTAGE.—

20 The adjustment percentage under this  
21 clause for a fiscal year is the weighted  
22 change in the 3-year average ending in the  
23 most recent year for which data are avail-  
24 able, over the 3-year average ending in the  
25 previous year, for—

1 “(I) the total number of human  
2 drug applications, efficacy supple-  
3 ments, and manufacturing supple-  
4 ments submitted to the Secretary;

5 “(II) the total number of active  
6 commercial investigational new drug  
7 applications; and

8 “(III) the total number of formal  
9 meetings scheduled by the Secretary,  
10 and written responses issued by the  
11 Secretary in lieu of such formal meet-  
12 ings, as identified in section I.H of  
13 the letters described in section 101(b)  
14 of the Prescription Drug User Fee  
15 Amendments of 2017.

16 “(C) CAPACITY PLANNING METHOD-  
17 OLOGY.—

18 “(i) DEVELOPMENT; EVALUATION  
19 AND REPORT.—The Secretary shall obtain,  
20 through a contract with an independent ac-  
21 counting or consulting firm, a report evalu-  
22 ating options and recommendations for a  
23 new methodology to accurately assess  
24 changes in the resource and capacity needs  
25 of the process for the review of human

1 drug applications. The capacity planning  
2 methodological options and recommenda-  
3 tions presented in such report shall utilize  
4 and be informed by personnel time report-  
5 ing data as an input. The report shall be  
6 published for public comment no later than  
7 the end of fiscal year 2020.

8 “(ii) ESTABLISHMENT AND IMPLE-  
9 MENTATION.—After review of the report  
10 described in clause (i) and any public com-  
11 ments thereon, the Secretary shall estab-  
12 lish a capacity planning methodology for  
13 purposes of this paragraph, which shall—

14 “(I) replace the interim method-  
15 ology under subparagraph (B);

16 “(II) incorporate such ap-  
17 proaches and attributes as the Sec-  
18 retary determines appropriate; and

19 “(III) be effective beginning with  
20 the first fiscal year for which fees are  
21 set after such capacity planning meth-  
22 odology is established.

23 “(D) LIMITATION.—Under no cir-  
24 cumstances shall an adjustment under this  
25 paragraph result in fee revenue for a fiscal year

1 that is less than the sum of the amounts under  
2 subsections (b)(1)(A) (the annual base revenue  
3 for the fiscal year) and (b)(1)(B) (the dollar  
4 amount of the inflation adjustment for the fis-  
5 cal year).

6 “(E) PUBLICATION IN FEDERAL REG-  
7 ISTER.—The Secretary shall publish in the Fed-  
8 eral Register notice under paragraph (5) the fee  
9 revenue and fees resulting from the adjustment  
10 and the methodologies under this paragraph.

11 “(3) OPERATING RESERVE ADJUSTMENT.—

12 “(A) INCREASE.—For fiscal year 2018 and  
13 subsequent fiscal years, the Secretary may, in  
14 addition to adjustments under paragraphs (1)  
15 and (2), further increase the fee revenue and  
16 fees if such an adjustment is necessary to pro-  
17 vide for not more than 14 weeks of operating  
18 reserves of carryover user fees for the process  
19 for the review of human drug applications.

20 “(B) DECREASE.—If the Secretary has  
21 carryover balances for such process in excess of  
22 14 weeks of such operating reserves, the Sec-  
23 retary shall decrease such fee revenue and fees  
24 to provide for not more than 14 weeks of such  
25 operating reserves.

1           “(C) NOTICE OF RATIONALE.—If an ad-  
2           justment under subparagraph (A) or (B) is  
3           made, the rationale for the amount of the in-  
4           crease or decrease (as applicable) in fee revenue  
5           and fees shall be contained in the annual Fed-  
6           eral Register notice under paragraph (5) estab-  
7           lishing fee revenue and fees for the fiscal year  
8           involved.

9           “(4) ADDITIONAL DIRECT COST ADJUST-  
10          MENT.—

11           “(A) IN GENERAL.—The Secretary shall,  
12           in addition to adjustments under paragraphs  
13           (1), (2), and (3), further increase the fee rev-  
14           enue and fees—

15           “(i) for fiscal year 2018, by  
16           \$8,730,000; and

17           “(ii) for fiscal year 2019 and subse-  
18           quent fiscal years, by the amount deter-  
19           mined under subparagraph (B).

20           “(B) AMOUNT.—The amount determined  
21           under this subparagraph is—

22           “(i) \$8,730,000, multiplied by

23           “(ii) the Consumer Price Index for  
24           urban consumers (Washington-Baltimore,  
25           DC-MD-VA-WV; Not Seasonally Adjusted;

1 All Items; Annual Index) for the most re-  
2 cent year of available data, divided by such  
3 Index for 2016.

4 “(5) ANNUAL FEE SETTING.—The Secretary  
5 shall, not later than 60 days before the start of each  
6 fiscal year that begins after September 30, 2017—

7 “(A) establish, for the next fiscal year,  
8 human drug application fees and prescription  
9 drug program fees under subsection (a), based  
10 on the revenue amounts established under sub-  
11 section (b) and the adjustments provided under  
12 this subsection; and

13 “(B) publish such fee revenue and fees in  
14 the Federal Register.

15 “(6) LIMIT.—The total amount of fees charged,  
16 as adjusted under this subsection, for a fiscal year  
17 may not exceed the total costs for such fiscal year  
18 for the resources allocated for the process for the re-  
19 view of human drug applications.”.

20 (d) FEE WAIVER OR REDUCTION.—Section 736(d) of  
21 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22 379h(d)) is amended—

23 (1) in paragraph (1)—

24 (A) by inserting “or” at the end of sub-  
25 paragraph (B);



1 (B) by striking subparagraph (C); and  
2 (C) by redesignating subparagraph (D) as  
3 subparagraph (C);  
4 (2) by striking paragraph (3) (relating to use of  
5 standard costs);  
6 (3) by redesignating paragraph (4) as para-  
7 graph (3); and  
8 (4) in paragraph (3), as so redesignated—  
9 (A) in subparagraphs (A) and (B), by  
10 striking “paragraph (1)(D)” and inserting  
11 “paragraph (1)(C)”; and  
12 (B) in subparagraph (B)—  
13 (i) by striking clause (ii);  
14 (ii) by striking “shall pay” through  
15 “(i) application fees” and inserting “shall  
16 pay application fees”; and  
17 (iii) by striking “; and” at the end  
18 and inserting a period.

19 (e) EFFECT OF FAILURE TO PAY FEES.—Section  
20 736(e) of the Federal Food, Drug, and Cosmetic Act (21  
21 U.S.C. 379h(e)) is amended by striking “all fees” and in-  
22 serting “all such fees”.

23 (f) LIMITATIONS.—Section 736(f)(2) of the Federal  
24 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(f)(2)) is  
25 amended by striking “supplements, prescription drug es-

1 tablishments, and prescription drug products” and insert-  
2 ing “prescription drug program fees”.

3 (g) CREDITING AND AVAILABILITY OF FEES.—Sec-  
4 tion 736(g) of the Federal Food, Drug, and Cosmetic Act  
5 (21 U.S.C. 379h(g)) is amended—

6 (1) in paragraph (3)—

7 (A) by striking “2013 through 2017” and  
8 inserting “2018 through 2022”; and

9 (B) by striking “and paragraph (4) of this  
10 subsection”; and

11 (2) by striking paragraph (4).

12 (h) ORPHAN DRUGS.—Section 736(k) of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 379h(k)) is  
14 amended by striking “product and establishment fees”  
15 each place it appears and inserting “prescription drug pro-  
16 gram fees”.

17 **SEC. 103. REAUTHORIZATION; REPORTING REQUIREMENTS.**

18 Section 736B of the Federal Food, Drug, and Cos-  
19 metic Act (21 U.S.C. 379h–2) is amended—

20 (1) in subsection (a)(1)—

21 (A) in the matter before subparagraph (A),  
22 by striking “2013” and inserting “2018”; and

23 (B) in subparagraph (A), by striking “Pre-  
24 scription Drug User Fee Amendments of 2012”

1 and inserting “Prescription Drug User Fee  
2 Amendments of 2017”;

3 (2) in subsection (b), by striking “2013” and  
4 inserting “2018”; and

5 (3) in subsection (d), by striking “2017” each  
6 place it appears and inserting “2022”.

7 **SEC. 104. SUNSET DATES.**

8 (a) AUTHORIZATION.—Sections 735 and 736 of the  
9 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g;  
10 379h) shall cease to be effective October 1, 2022.

11 (b) REPORTING REQUIREMENTS.—Section 736B of  
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 379h–2) shall cease to be effective January 31, 2023.

14 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-  
15 ber 1, 2017, subsections (a) and (b) of section 105 of the  
16 Food and Drug Administration Safety and Innovation Act  
17 (Public Law 112–144) are repealed.

18 **SEC. 105. EFFECTIVE DATE.**

19 The amendments made by this title shall take effect  
20 on October 1, 2017, or the date of the enactment of this  
21 Act, whichever is later, except that fees under part 2 of  
22 subchapter C of chapter VII of the Federal Food, Drug,  
23 and Cosmetic Act shall be assessed for all human drug  
24 applications received on or after October 1, 2017, regard-  
25 less of the date of the enactment of this Act.

1 **SEC. 106. SAVINGS CLAUSE.**

2       Notwithstanding the amendments made by this title,  
3 part 2 of subchapter C of chapter VII of the Federal Food,  
4 Drug, and Cosmetic Act, as in effect on the day before  
5 the date of the enactment of this title, shall continue to  
6 be in effect with respect to human drug applications and  
7 supplements (as defined in such part as of such day) that  
8 on or after October 1, 2012, but before October 1, 2017,  
9 were accepted by the Food and Drug Administration for  
10 filing with respect to assessing and collecting any fee re-  
11 quired by such part for a fiscal year prior to fiscal year  
12 2018.

13 **TITLE II—FEES RELATING TO**  
14 **DEVICES**

15 **SEC. 201. SHORT TITLE; FINDINGS.**

16       (a) **SHORT TITLE.**—This title may be cited as the  
17 “Medical Device User Fee Amendments of 2017”.

18       (b) **FINDINGS.**—The Congress finds that the fees au-  
19 thorized under the amendments made by this title will be  
20 dedicated toward expediting the process for the review of  
21 device applications and for assuring the safety and effec-  
22 tiveness of devices, as set forth in the goals identified for  
23 purposes of part 3 of subchapter C of chapter VII of the  
24 Federal Food, Drug, and Cosmetic Act in the letters from  
25 the Secretary of Health and Human Services to the Chair-  
26 man of the Committee on Health, Education, Labor, and

1 Pensions of the Senate and the Chairman of the Com-  
2 mittee on Energy and Commerce of the House of Rep-  
3 resentatives, as set forth in the Congressional Record.

4 **SEC. 202. DEFINITIONS.**

5 Section 737 of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 379i) is amended—

7 (1) by redesignating paragraphs (8) through  
8 (13) as paragraphs (9) through (14), respectively;

9 (2) by inserting after paragraph (7) the fol-  
10 lowing new paragraph:

11 “(8) The term ‘de novo classification request’  
12 means a request made under section 513(f)(2)(A)  
13 with respect to the classification of a device.”;

14 (3) in subparagraph (D) of paragraph (10) (as  
15 redesignated by paragraph (1)), by striking “and  
16 submissions” and inserting “submissions, and de  
17 novo classification requests”; and

18 (4) in paragraph (11) (as redesignated by para-  
19 graph (1)), by striking “2011” and inserting  
20 “2016”.

21 **SEC. 203. AUTHORITY TO ASSESS AND USE DEVICE FEES.**

22 (a) TYPES OF FEES.—Section 738(a) of the Federal  
23 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(a)) is  
24 amended—

1 (1) in paragraph (1), by striking “fiscal year  
2 2013” and inserting “fiscal year 2018”; and

3 (2) in paragraph (2)—

4 (A) in subparagraph (A)—

5 (i) in the matter preceding clause (i),  
6 by striking “October 1, 2012” and insert-  
7 ing “October 1, 2017”;

8 (ii) in clause (viii), by striking “2”  
9 and inserting “3.4”; and

10 (iii) by adding at the end the fol-  
11 lowing new clause:

12 “(xi) For a de novo classification re-  
13 quest, a fee equal to 30 percent of the fee  
14 that applies under clause (i).”; and

15 (B) in subparagraph (B)(v)(I), by striking  
16 “or premarket notification submission” and in-  
17 serting “premarket notification submission, or  
18 de novo classification request”.

19 (b) FEE AMOUNTS.—Section 738(b) of the Federal  
20 Food, Drug, and Cosmetic Act (21 U.S.C. 379j(b)) is  
21 amended to read as follows:

22 “(b) FEE AMOUNTS.—

23 “(1) IN GENERAL.—Subject to subsections (c),  
24 (d), (e), and (h), for each of fiscal years 2018  
25 through 2022, fees under subsection (a) shall be de-

1 rived from the base fee amounts specified in para-  
 2 graph (2), to generate the total revenue amounts  
 3 specified in paragraph (3).

4 “(2) BASE FEE AMOUNTS SPECIFIED.—For  
 5 purposes of paragraph (1), the base fee amounts  
 6 specified in this paragraph are as follows:

“Fee Type	Fiscal Year 2018	Fiscal Year 2019	Fiscal Year 2020	Fiscal Year 2021	Fiscal Year 2022
Premarket Application .....	\$294,000	\$300,000	\$310,000	\$328,000	\$329,000
Establishment Registration .....	\$4,375	\$4,548	\$4,760	\$4,975	\$4,978

7 “(3) TOTAL REVENUE AMOUNTS SPECIFIED.—  
 8 For purposes of paragraph (1), the total revenue  
 9 amounts specified in this paragraph are as follows:

10 “(A) \$183,280,756 for fiscal year 2018.

11 “(B) \$190,654,875 for fiscal year 2019.

12 “(C) \$200,132,014 for fiscal year 2020.

13 “(D) \$211,748,789 for fiscal year 2021.

14 “(E) \$213,687,660 for fiscal year 2022.”.

15 (c) ANNUAL FEE SETTING; ADJUSTMENTS.—Section  
 16 738(c) of the Federal Food, Drug, and Cosmetic Act (21  
 17 U.S.C. 379j(c)) is amended—

18 (1) in paragraph (1), by striking “2012” and  
 19 inserting “2017”;

20 (2) in paragraph (2)—

21 (A) in subparagraph (A), by striking  
 22 “2014” and inserting “2018”;

1 (B) by striking subparagraph (B) and in-  
2 serting the following new subparagraph:

3 “(B) APPLICABLE INFLATION ADJUST-  
4 MENT.—The applicable inflation adjustment for  
5 fiscal year 2018 and each subsequent fiscal  
6 year is the product of—

7 “(i) the base inflation adjustment  
8 under subparagraph (C) for such fiscal  
9 year; and

10 “(ii) the product of the base inflation  
11 adjustment under subparagraph (C) for  
12 each of the fiscal years preceding such fis-  
13 cal year, beginning with fiscal year 2016.”;

14 (C) in subparagraph (C), in the heading,  
15 by striking “TO TOTAL REVENUE AMOUNTS”;  
16 and

17 (D) by amending subparagraph (D) to  
18 read as follows:

19 “(D) ADJUSTMENT TO BASE FEE  
20 AMOUNTS.—For each of fiscal years 2018  
21 through 2022, the Secretary shall—

22 “(i) adjust the base fee amounts spec-  
23 ified in subsection (b)(2) for such fiscal  
24 year by multiplying such amounts by the



1 applicable inflation adjustment under sub-  
2 paragraph (B) for such year; and

3 “(ii) if the Secretary determines nec-  
4 essary, increase (in addition to the adjust-  
5 ment under clause (i)) such base fee  
6 amounts, on a uniform proportionate basis,  
7 to generate the total revenue amounts  
8 under subsection (b)(3), as adjusted for in-  
9 flation under subparagraph (A).”; and

10 (3) in paragraph (3)—

11 (A) by striking “2014 through 2017” and  
12 inserting “2018 through 2022”; and

13 (B) by striking “further adjusted” and in-  
14 serting “increased”.

15 (d) SMALL BUSINESSES; FEE WAIVER AND FEE RE-  
16 Duction REGARDING PREMARKET APPROVAL FEES.—  
17 Section 738(d) of the Federal Food, Drug, and Cosmetic  
18 Act (21 U.S.C. 379j(d)) is amended—

19 (1) in paragraph (1), by striking “specified in  
20 clauses (i) through (v) and clauses (vii), (ix), and  
21 (x)” and inserting “specified in clauses (i) through  
22 (vii) and clauses (ix), (x), and (xi)”; and

23 (2) in paragraph (2)(C)—

24 (A) by striking “supplement, or” and in-  
25 serting “supplement,”; and

1 (B) by inserting “, or a de novo classifica-  
2 tion request” after “class III device”.

3 (e) SMALL BUSINESSES; FEE REDUCTION REGARD-  
4 ING PREMARKET NOTIFICATION SUBMISSIONS.—Section  
5 738(e)(2)(C) of the Federal Food, Drug, and Cosmetic  
6 Act (21 U.S.C. 379j(e)(2)(C)) is amended by striking  
7 “50” and inserting “25”.

8 (f) FEE WAIVER OR REDUCTION.—

9 (1) REPEAL.—Section 738 of the Federal Food,  
10 Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-  
11 ed by striking subsection (f).

12 (2) CONFORMING CHANGES.—

13 (A) Section 515(c)(4)(A) of the Federal  
14 Food, Drug, and Cosmetic Act (21 U.S.C.  
15 360e(c)(4)(A)) is amended by striking “738(h)”  
16 and inserting “738(g)”.

17 (B) Section 738 of the Federal Food,  
18 Drug, and Cosmetic Act (21 U.S.C. 379j), as  
19 amended by paragraph (1), is further amend-  
20 ed—

21 (i) by redesignating subsections (g)  
22 through (l) as subsections (f) through (k);

23 (ii) in subsection (a)(2)(A), by strik-  
24 ing “(d), (e), and (f)” and inserting “(d)  
25 and (e)”; and

1 (iii) in subsection (a)(3)(A), by strik-  
2 ing “and subsection (f)”.

3 (g) EFFECT OF FAILURE TO PAY FEES.—Subsection  
4 (f)(1), as redesignated, of section 738 of the Federal  
5 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-  
6 ed—

7 (1) by striking “or periodic reporting con-  
8 cerning a class III device” and inserting “periodic  
9 reporting concerning a class III device, or de novo  
10 classification request”; and

11 (2) by striking “all fees” and inserting “all  
12 such fees”.

13 (h) CONDITIONS.—Subsection (g)(1)(A), as redesign-  
14 nated, of section 738 of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 379j) is amended by striking  
16 “\$280,587,000” and inserting “\$320,825,000”.

17 (i) CREDITING AND AVAILABILITY OF FEES.—Sub-  
18 section (h), as redesignated, of section 738 of the Federal  
19 Food, Drug, and Cosmetic Act (21 U.S.C. 379j) is amend-  
20 ed—

21 (1) in paragraph (3)—

22 (A) by striking “2013 through 2017” and  
23 inserting “2018 through 2022”; and

1 (B) by striking “subsection (c)” and all  
2 that follows through the period at the end and  
3 inserting “subsection (c).”; and  
4 (2) by striking paragraph (4).

5 **SEC. 204. REAUTHORIZATION; REPORTING REQUIREMENTS.**

6 (a) PERFORMANCE REPORTS.—Section 738A(a) of  
7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
8 379j–1(a)) is amended—

9 (1) in paragraph (1)—

10 (A) in subparagraph (A)—

11 (i) by striking “2013” and inserting  
12 “2018”; and

13 (ii) by striking “the Medical Device  
14 User Fee Amendments of 2012” and in-  
15 serting “Medical Device User Fee Amend-  
16 ments of 2017”; and

17 (B) in subparagraph (B), by striking “the  
18 Medical Device User Fee Amendments of  
19 2012” and inserting “Medical Device User Fee  
20 Amendments of 2017”; and

21 (2) in paragraph (2), by striking “2013  
22 through 2017” and inserting “2018 through 2022”.

23 (b) REAUTHORIZATION.—Section 738A(b) of the  
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
25 1(b)) is amended—

1 (1) in paragraph (1), by striking “2017” and  
2 inserting “2022”; and

3 (2) in paragraph (5), by striking “2017” and  
4 inserting “2022”.

5 **SEC. 205. CONFORMITY ASSESSMENT PILOT PROGRAM.**

6 (a) IN GENERAL.—Section 514 of the Federal Food,  
7 Drug, and Cosmetic Act (21 U.S.C. 360d) is amended by  
8 adding at the end the following:

9 “(d) PILOT ACCREDITATION SCHEME FOR CON-  
10 FORMITY ASSESSMENT.—

11 “(1) IN GENERAL.—The Secretary shall estab-  
12 lish a pilot program under which—

13 “(A) testing laboratories may be accred-  
14 ited, by accreditation bodies meeting criteria  
15 specified by the Secretary, to assess the con-  
16 formance of a device with certain standards rec-  
17 ognized under this section; and

18 “(B) subject to paragraph (2), determina-  
19 tions by testing laboratories so accredited that  
20 a device conforms with such standard or stand-  
21 ards shall be accepted by the Secretary for pur-  
22 poses of demonstrating such conformity under  
23 this section unless the Secretary finds that a  
24 particular such determination shall not be so  
25 accepted.

1           “(2) SECRETARIAL REVIEW OF ACCREDITED  
2       LABORATORY DETERMINATIONS.—The Secretary  
3       may—

4           “(A) review determinations by testing lab-  
5       oratories accredited pursuant to this subsection,  
6       including by conducting periodic audits of such  
7       determinations or processes of accredited bodies  
8       or testing laboratories and, following such re-  
9       view, taking additional measures under this  
10      Act, such as suspension or withdrawal of ac-  
11      creditation of such testing laboratory under  
12      paragraph (1)(A) or requesting additional infor-  
13      mation with respect to such device, as the Sec-  
14      retary determines appropriate; and

15          “(B) if the Secretary becomes aware of in-  
16      formation materially bearing on safety or effec-  
17      tiveness of a device assessed for conformity by  
18      a testing laboratory so accredited, take such ad-  
19      ditional measures under this Act as the Sec-  
20      retary determines appropriate, such as suspen-  
21      sion or withdrawal of accreditation of such test-  
22      ing laboratory under paragraph (1)(A), or re-  
23      questing additional information with regard to  
24      such device.

25          “(3) IMPLEMENTATION AND REPORTING.—

1           “(A) PUBLIC MEETING.—The Secretary  
2           shall publish in the Federal Register a notice of  
3           a public meeting to be held no later than Sep-  
4           tember 30, 2018, to discuss and obtain input  
5           and recommendations from stakeholders regard-  
6           ing the goals and scope of, and a suitable  
7           framework and procedures and requirements  
8           for, the pilot program under this subsection.

9           “(B) PILOT PROGRAM GUIDANCE.—The  
10          Secretary shall—

11               “(i) not later than September 30,  
12               2019, issue draft guidance regarding the  
13               goals and implementation of the pilot pro-  
14               gram under this subsection; and

15               “(ii) not later than September 30,  
16               2021, issue final guidance with respect to  
17               the implementation of such program.

18          “(C) PILOT PROGRAM INITIATION.—Not  
19          later than September 30, 2020, the Secretary  
20          shall initiate the pilot program under this sub-  
21          section.

22          “(D) REPORT.—The Secretary shall make  
23          available on the website of the Food and Drug  
24          Administration an annual report on the

1 progress of the pilot program under this sub-  
2 section.

3 “(4) SUNSET.—As of October 1, 2022—

4 “(A) the authority for accreditation bodies  
5 to accredit testing laboratories pursuant to  
6 paragraph (1)(A) shall cease to have force or  
7 effect;

8 “(B) the Secretary—

9 “(i) may not accept a determination  
10 pursuant to paragraph (1)(B) made by a  
11 testing laboratory after such date; and

12 “(ii) may accept such a determination  
13 made prior to such date;

14 “(C) except for purposes of accepting a de-  
15 termination described in subparagraph (B)(ii),  
16 the Secretary shall not continue to recognize  
17 the accreditation of testing laboratories accred-  
18 ited under paragraph (1)(A); and

19 “(D) the Secretary may take actions in ac-  
20 cordance with paragraph (2) with respect to the  
21 determinations made prior to such date and  
22 recognition of the accreditation of testing lab-  
23 oratories pursuant to determinations made  
24 prior to such date.”.



1 **SEC. 206. REAUTHORIZATION OF REVIEW.**

2 Section 523 of the Federal Food, Drug, and Cosmetic  
3 Act (21 U.S.C. 360m) is amended—

4 (1) in subsection (a)(3)—

5 (A) in subparagraph (A), by striking  
6 clauses (ii) and (iii) and inserting the following:

7 “(ii) a device classified under section  
8 513(f)(2) or designated under section  
9 515C(d); or

10 “(iii) a device that is of a type, or  
11 subset of a type, listed as not eligible for  
12 review under subparagraph (B)(iii).”;

13 (B) by striking subparagraph (B) and in-  
14 serting the following:

15 “(B) DESIGNATION FOR REVIEW.—The  
16 Secretary shall—

17 “(i) issue draft guidance on the fac-  
18 tors the Secretary will use in determining  
19 whether a class I or class II device type, or  
20 subset of such device types, is eligible for  
21 review by an accredited person, includ-  
22 ing—

23 “(I) the risk of the device type,  
24 or subset of such device type; and

25 “(II) whether the device type, or  
26 subset of such device type, is perma-

1 nently implantable, life sustaining, or  
2 life supporting;

3 “(ii) not later than 24 months after  
4 the date on which the Secretary issues  
5 such draft guidance, finalize such guid-  
6 ance; and

7 “(iii) beginning on the date such guid-  
8 ance is finalized, designate and post on the  
9 Internet website of the Food and Drug Ad-  
10 ministration, an updated list of class I and  
11 class II device types, or subsets of such de-  
12 vice types, and the Secretary’s determina-  
13 tion with respect to whether each such de-  
14 vice type, or subset of a device type, is eli-  
15 gible or not eligible for review by an ac-  
16 credited person under this section based on  
17 the factors described in clause (i).”; and

18 (C) by adding at the end the following:

19 “(C) INTERIM RULE.—Until the date on  
20 which the updated list is designated and posted  
21 in accordance with subparagraph (B)(iii), the  
22 list in effect on the date of enactment the Med-  
23 ical Device User Fee Amendments of 2017 shall  
24 be in effect.”;

25 (2) in subsection (b)—

1 (A) in paragraph (2)—

2 (i) by striking subparagraph (D); and

3 (ii) by redesignating subparagraph

4 (E) as subparagraph (D); and

5 (B) in paragraph (3)—

6 (i) by redesignating subparagraph (E)

7 as subparagraph (F);

8 (ii) in subparagraph (F) (as so redes-

9 ignated), by striking “The operations of”

10 and all that follows through “it will—”

11 and inserting “Such person shall agree, at

12 a minimum, to include in its request for

13 accreditation a commitment to, at the time

14 of accreditation, and at any time it is per-

15 forming any review pursuant to this sec-

16 tion—”; and

17 (iii) by inserting after subparagraph

18 (D) the following new subparagraph:

19 “(E) The operations of such person shall

20 be in accordance with generally accepted profes-

21 sional and ethical business practices.”; and

22 (3) in subsection (c), by striking “2017” and

23 inserting “2022”.

1 **SEC. 207. ELECTRONIC FORMAT FOR SUBMISSIONS.**

2 Section 745A(b) of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 379k–1(b)) is amended by adding  
4 at the end the following new paragraph:

5 “(3) PRESUBMISSIONS AND SUBMISSIONS SOLE-  
6 LY IN ELECTRONIC FORMAT.—

7 “(A) IN GENERAL.—Beginning on such  
8 date as the Secretary specifies in final guidance  
9 issued under subparagraph (C), presubmissions  
10 and submissions for devices described in para-  
11 graph (1) (and any appeals of action taken by  
12 the Secretary with respect to such  
13 presubmissions or submissions) shall be sub-  
14 mitted solely in such electronic format as speci-  
15 fied by the Secretary in such guidance.

16 “(B) DRAFT GUIDANCE.—The Secretary  
17 shall, not later than October 1, 2019, issue  
18 draft guidance providing for—

19 “(i) any further standards for the  
20 submission by electronic format required  
21 under subparagraph (A);

22 “(ii) a timetable for the establishment  
23 by the Secretary of such further standards;  
24 and

1 “(iii) criteria for waivers of and ex-  
2 emptions from the requirements of this  
3 subsection.

4 “(C) FINAL GUIDANCE.—The Secretary  
5 shall, not later than 12 months after the close  
6 of the public comment period on the draft guid-  
7 ance issued under subparagraph (B), issue final  
8 guidance described in clauses (i) through (iii) of  
9 such subparagraph.”.

10 **SEC. 208. SAVINGS CLAUSE.**

11 Notwithstanding the amendments made by this title,  
12 part 3 of subchapter C of chapter VII of the Federal Food,  
13 Drug, and Cosmetic Act (21 U.S.C. 379i et seq.), as in  
14 effect on the day before the date of the enactment of this  
15 title, shall continue to be in effect with respect to the sub-  
16 missions listed in section 738(a)(2)(A) of such Act (as de-  
17 fined in such part as of such day) that on or after October  
18 1, 2012, but before October 1, 2017, were accepted by  
19 the Food and Drug Administration for filing with respect  
20 to assessing and collecting any fee required by such part  
21 for a fiscal year prior to fiscal year 2018.

22 **SEC. 209. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect  
24 on October 1, 2017, or the date of the enactment of this  
25 Act, whichever is later, except that fees under part 3 of

1 subchapter C of chapter VII of the Federal Food, Drug,  
2 and Cosmetic Act shall be assessed for all submissions list-  
3 ed in section 738(a)(2)(A) of such Act received on or after  
4 October 1, 2017, regardless of the date of the enactment  
5 of this Act.

6 **SEC. 210. SUNSET CLAUSE.**

7 (a) AUTHORIZATION.—Sections 737 and 738 of the  
8 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 739i;  
9 739j) shall cease to be effective October 1, 2022.

10 (b) REPORTING REQUIREMENTS.—Section 738A (21  
11 U.S.C. 739j–1) of the Federal Food, Drug, and Cosmetic  
12 Act (regarding reauthorization and reporting require-  
13 ments) shall cease to be effective January 31, 2023.

14 (c) PREVIOUS SUNSET PROVISION.—

15 (1) IN GENERAL.—Effective October 1, 2017,  
16 section 207(a) of the Medical Device User Fee  
17 Amendments of 2012 (Public Law 112–144) is re-  
18 pealed.

19 (2) CONFORMING AMENDMENT.—The Food and  
20 Drug Administration Safety and Innovation Act  
21 (Public Law 112–144) is amended in the table of  
22 contents in section 2 by striking the item relating to  
23 section 207.

1     **TITLE III—FEES RELATING TO**  
2                   **GENERIC DRUGS**

3     **SEC. 301. SHORT TITLE; FINDING.**

4         (a) SHORT TITLE.—This title may be cited as the  
5     “Generic Drug User Fee Amendments of 2017”.

6         (b) FINDING.—The Congress finds that the fees au-  
7     thorized by the amendments made in this title will be dedi-  
8     cated to human generic drug activities, as set forth in the  
9     goals identified for purposes of part 7 of subchapter C  
10    of chapter VII of the Federal Food, Drug, and Cosmetic  
11    Act, in the letters from the Secretary of Health and  
12    Human Services to the Chairman of the Committee on  
13    Health, Education, Labor, and Pensions of the Senate and  
14    the Chairman of the Committee on Energy and Commerce  
15    of the House of Representatives, as set forth in the Con-  
16    gressional Record.

17    **SEC. 302. DEFINITIONS.**

18         Section 744A of the Federal Food, Drug, and Cos-  
19     metic Act (21 U.S.C. 379j–41) is amended—

20             (1) in paragraph (1)(B), by striking “applica-  
21             tion for a positron emission tomography drug.” and  
22             inserting “application—

23                     “(i) for a positron emission tomog-  
24                     raphy drug; or

1 “(ii) submitted by a State or Federal  
2 governmental entity for a drug that is not  
3 distributed commercially.”;

4 (2) by redesignating paragraphs (5) through  
5 (12) as paragraphs (6) through (13), respectively;  
6 and

7 (3) by inserting after paragraph (4) the fol-  
8 lowing:

9 “(5) The term ‘contract manufacturing organi-  
10 zation facility’ means a manufacturing facility of a  
11 finished dosage form of a drug approved pursuant to  
12 an abbreviated new drug application, where such  
13 manufacturing facility is not identified in an ap-  
14 proved abbreviated new drug application held by the  
15 owner of such facility or an affiliate of such owner  
16 or facility.”.

17 **SEC. 303. AUTHORITY TO ASSESS AND USE HUMAN GE-**  
18 **NERIC DRUG FEES.**

19 (a) TYPES OF FEES.—Section 744B(a) of the Fed-  
20 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
21 42(a)) is amended—

22 (1) in the matter preceding paragraph (1), by  
23 striking “fiscal year 2013” and inserting “fiscal year  
24 2018”;



1           (2) in paragraph (1), by adding at the end the  
2       following:

3           “(E) SUNSET.—This paragraph shall cease  
4       to be effective October 1, 2022.”;

5       (3) in paragraph (2)—

6           (A) by amending subparagraph (C) to read  
7       as follows:

8           “(C) NOTICE.—Not later than 60 days be-  
9       fore the start of each of fiscal years 2018  
10      through 2022, the Secretary shall publish in the  
11      Federal Register the amount of the drug mas-  
12      ter file fee established by this paragraph for  
13      such fiscal year.”; and

14      (B) in subparagraph (E)—

15          (i) in clause (i)—

16              (I) by striking “no later than the  
17              date” and inserting “on the earlier  
18              of—

19                  “(I) the date”;

20              (II) by striking the period and  
21              inserting “; or”; and

22              (III) by adding at the end the  
23      following:

1 “(II) the date on which the drug  
2 master file holder requests the initial  
3 completeness assessment.”; and

4 (ii) in clause (ii), by striking “notice  
5 provided for in clause (i) or (ii) of subpara-  
6 graph (C), as applicable” and inserting  
7 “notice provided for in subparagraph (C)”;

8 (4) in paragraph (3)—

9 (A) in the heading, by striking “AND  
10 PRIOR APPROVAL SUPPLEMENT”;

11 (B) in subparagraph (A), by striking “or a  
12 prior approval supplement to an abbreviated  
13 new drug application”;

14 (C) by amending subparagraphs (B) and  
15 (C) to read as follows:

16 “(B) NOTICE.—Not later than 60 days be-  
17 fore the start of each of fiscal years 2018  
18 through 2022, the Secretary shall publish in the  
19 Federal Register the amount of the fees under  
20 subparagraph (A) for such fiscal year.

21 “(C) FEE DUE DATE.—The fees required  
22 by subparagraphs (A) and (F) shall be due no  
23 later than the date of submission of the abbrevi-  
24 ated new drug application or prior approval  
25 supplement for which such fee applies.”;

1 (D) in subparagraph (D)—

2 (i) in the heading, by inserting “, IS  
3 WITHDRAWN PRIOR TO BEING RECEIVED,  
4 OR IS NO LONGER RECEIVED” after “RE-  
5 CEIVED”; and

6 (ii) by striking “The Secretary shall”  
7 and all that follows through the period and  
8 inserting the following:

9 “(i) APPLICATIONS NOT CONSIDERED  
10 TO HAVE BEEN RECEIVED AND APPLICA-  
11 TIONS WITHDRAWN PRIOR TO BEING RE-  
12 CEIVED.—The Secretary shall refund 75  
13 percent of the fee paid under subparagraph  
14 (A) for any abbreviated new drug applica-  
15 tion that the Secretary considers not to  
16 have been received within the meaning of  
17 section 505(j)(5)(A) for a cause other than  
18 failure to pay fees, or that has been with-  
19 drawn prior to being received within the  
20 meaning of section 505(j)(5)(A).

21 “(ii) APPLICATIONS NO LONGER RE-  
22 CEIVED.—The Secretary shall refund 100  
23 percent of the fee paid under subparagraph  
24 (A) for any abbreviated new drug applica-  
25 tion if the Secretary initially receives the

1 application under section 505(j)(5)(A) and  
2 subsequently determines that an exclusivity  
3 period for a listed drug should have pre-  
4 vented the Secretary from receiving such  
5 application, such that the abbreviated new  
6 drug application is no longer received with-  
7 in the meaning of section 505(j)(5)(A).”;

8 (E) in subparagraph (E), by striking “or  
9 prior approval supplement”; and

10 (F) in the matter preceding clause (i) of  
11 subparagraph (F)—

12 (i) by striking “2012” and inserting  
13 “2017”; and

14 (ii) by striking “subsection (d)(3)”  
15 and inserting “subsection (d)(2)”;

16 (5) in paragraph (4)—

17 (A) in subparagraph (A)—

18 (i) in the matter preceding clause (i)  
19 and in clause (iii), by striking “, or in-  
20 tended to be identified, in at least one ge-  
21 neric drug submission that is pending or”  
22 and inserting “in at least one generic drug  
23 submission that is”;

24 (ii) in clause (i), by striking “or in-  
25 tended to be identified in at least one ge-

1           neric drug submission that is pending or”  
2           and inserting “in at least one generic drug  
3           submission that is”;

4           (iii) in clause (ii), by striking “pro-  
5           duces,” and all that follows through “such  
6           a” and inserting “is identified in at least  
7           one generic drug submission in which the  
8           facility is approved to produce one or more  
9           active pharmaceutical ingredients or in a  
10          Type II active pharmaceutical ingredient  
11          drug master file referenced in at least one  
12          such”; and

13          (iv) in clause (iii), by striking “to fees  
14          under both such clauses” and inserting  
15          “only to the fee attributable to the manu-  
16          facture of the finished dosage forms”; and

17          (B) by amending subparagraphs (C) and  
18          (D) to read as follows:

19               “(C) NOTICE.—Within the timeframe spec-  
20               ified in subsection (d)(1), the Secretary shall  
21               publish in the Federal Register the amount of  
22               the fees under subparagraph (A) for such fiscal  
23               year.

24               “(D) FEE DUE DATE.—For each of fiscal  
25               years 2018 through 2022, the fees under sub-

1 paragraph (A) for such fiscal year shall be due  
2 on the later of—

3 “(i) the first business day on or after  
4 October 1 of each such year; or

5 “(ii) the first business day after the  
6 enactment of an appropriations Act pro-  
7 viding for the collection and obligation of  
8 fees for such year under this section for  
9 such year.”;

10 (6) by redesignating paragraph (5) as para-  
11 graph (6); and

12 (7) by inserting after paragraph (4) the fol-  
13 lowing:

14 “(5) GENERIC DRUG APPLICANT PROGRAM  
15 FEE.—

16 “(A) IN GENERAL.—A generic drug appli-  
17 cant program fee shall be assessed annually as  
18 described in subsection (b)(2)(E).

19 “(B) AMOUNT.—The amount of fees estab-  
20 lished under subparagraph (A) shall be estab-  
21 lished under subsection (d).

22 “(C) NOTICE.—Within the timeframe spec-  
23 ified in subsection (d)(1), the Secretary shall  
24 publish in the Federal Register the amount of

1 the fees under subparagraph (A) for such fiscal  
2 year.

3 “(D) FEE DUE DATE.—For each of fiscal  
4 years 2018 through 2022, the fees under sub-  
5 paragraph (A) for such fiscal year shall be due  
6 on the later of—

7 “(i) the first business day on or after  
8 October 1 of each such fiscal year; or

9 “(ii) the first business day after the  
10 date of enactment of an appropriations Act  
11 providing for the collection and obligation  
12 of fees for such fiscal year under this sec-  
13 tion for such fiscal year.”.

14 (b) FEE REVENUE AMOUNTS.—Section 744B(b) of  
15 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
16 379j–42(b)) is amended—

17 (1) in paragraph (1)—

18 (A) in subparagraph (A)—

19 (i) in the heading, by striking “2013”  
20 and inserting “2018”;

21 (ii) by striking “2013” and inserting  
22 “2018”;

23 (iii) by striking “\$299,000,000” and  
24 inserting “\$493,600,000”; and

1 (iv) by striking “Of that amount” and  
2 all that follows through the end of clause  
3 (ii); and

4 (B) in subparagraph (B)—

5 (i) in the heading, by striking “2014  
6 THROUGH 2017” and inserting “2019  
7 THROUGH 2022”;

8 (ii) by striking “2014 through 2017”  
9 and inserting “2019 through 2022”;

10 (iii) by striking “paragraphs (2)  
11 through (4)” and inserting “paragraphs  
12 (2) through (5)”;

13 (iv) by striking “\$299,000,000” and  
14 inserting “\$493,600,000”; and

15 (2) in paragraph (2)—

16 (A) in the matter preceding subparagraph  
17 (A)—

18 (i) by striking “paragraph (1)(A)(ii)  
19 for fiscal year 2013 and paragraph (1)(B)  
20 for each of fiscal years 2014 through  
21 2017” and inserting “such paragraph for a  
22 fiscal year”; and

23 (ii) by striking “through (4)” and in-  
24 serting “through (5)”;



1 (B) in subparagraph (A), by striking “Six  
2 percent” and inserting “Five percent”;

3 (C) by amending subparagraphs (B) and  
4 (C) to read as follows:

5 “(B) Thirty-three percent shall be derived  
6 from fees under subsection (a)(3) (relating to  
7 abbreviated new drug applications).

8 “(C) Twenty percent shall be derived from  
9 fees under subsection (a)(4)(A)(i) (relating to  
10 generic drug facilities). The amount of the fee  
11 for a contract manufacturing organization facil-  
12 ity shall be equal to one-third the amount of the  
13 fee for a facility that is not a contract manufac-  
14 turing organization facility. The amount of the  
15 fee for a facility located outside the United  
16 States and its territories and possessions shall  
17 be \$15,000 higher than the amount of the fee  
18 for a facility located in the United States and  
19 its territories and possessions.”;

20 (D) in subparagraph (D)—

21 (i) by striking “Fourteen percent”  
22 and inserting “Seven percent”;

23 (ii) by striking “not less than \$15,000  
24 and not more than \$30,000” and inserting  
25 “\$15,000”; and

1 (iii) by striking “, as determined” and  
2 all that follows through the period at the  
3 end and inserting a period; and  
4 (E) by adding at the end the following:

5 “(E)(i) Thirty-five percent shall be derived  
6 from fees under subsection (a)(5) (relating to  
7 generic drug applicant program fees). For pur-  
8 poses of this subparagraph, if a person has af-  
9 filiates, a single program fee shall be assessed  
10 with respect to that person, including its affili-  
11 ates, and may be paid by that person or any  
12 one of its affiliates. The Secretary shall deter-  
13 mine the fees as follows:

14 “(I) If a person (including its affili-  
15 ates) owns at least one but not more than  
16 5 approved abbreviated new drug applica-  
17 tions on the due date for the fee under this  
18 subsection, the person (including its affili-  
19 ates) shall be assessed a small business ge-  
20 neric drug applicant program fee equal to  
21 one-tenth of the large size operation ge-  
22 neric drug applicant program fee.

23 “(II) If a person (including its affili-  
24 ates) owns at least 6 but not more than 19  
25 approved abbreviated new drug applica-

tions on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a medium size operation generic drug applicant program fee equal to two-fifths of the large size operation generic drug applicant program fee.

“(III) If a person (including its affiliates) owns 20 or more approved abbreviated new drug applications on the due date for the fee under this subsection, the person (including its affiliates) shall be assessed a large size operation generic drug applicant program fee.

“(ii) For purposes of this subparagraph, an abbreviated new drug application shall be deemed not to be approved if the applicant has submitted a written request for withdrawal of approval of such abbreviated new drug application by April 1 of the previous fiscal year.”.

(c) ADJUSTMENTS.—Section 744B(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–42(c)) is amended—

(1) in paragraph (1)—

(A) by striking “2014” and inserting “2019”;

1 (B) by inserting “to equal the product of  
2 the total revenues established in such notice for  
3 the prior fiscal year multiplied” after “a fiscal  
4 year,”; and

5 (C) by striking the flush text following  
6 subparagraph (C); and

7 (2) in paragraph (2)—

8 (A) by striking “2017” each place it ap-  
9 pears and inserting “2022”;

10 (B) by striking “the first 3 months of fis-  
11 cal year 2018” and inserting “the first 3  
12 months of fiscal year 2023”; and

13 (C) by striking “Such fees may only be  
14 used in fiscal year 2018.”.

15 (d) ANNUAL FEE SETTING.—Section 744B(d) of the  
16 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
17 42(d)) is amended—

18 (1) by striking paragraphs (1) and (2) and in-  
19 serting the following:

20 “(1) FISCAL YEARS 2018 THROUGH 2022.—Not  
21 more than 60 days before the first day of each of  
22 fiscal years 2018 through 2022, the Secretary shall  
23 establish the fees described in paragraphs (2)  
24 through (5) of subsection (a), based on the revenue

1 amounts established under subsection (b) and the  
2 adjustments provided under subsection (c).”;

3 (2) by redesignating paragraph (3) as para-  
4 graph (2); and

5 (3) in paragraph (2) (as so redesignated), in  
6 the matter preceding subparagraph (A), by striking  
7 “fees under paragraphs (1) and (2)” and inserting  
8 “fee under paragraph (1)”.

9 (e) IDENTIFICATION OF FACILITIES.—Section  
10 744B(f) of the Federal Food, Drug, and Cosmetic Act (21  
11 U.S.C. 379j–42(f)) is amended—

12 (1) by striking paragraph (1);

13 (2) by redesignating paragraphs (2) through  
14 (4) as paragraphs (1) through (3), respectively;

15 (3) in paragraph (1) (as so redesignated)—

16 (A) by striking “paragraph (4)” and in-  
17 serting “paragraph (3)”; and

18 (B) by striking “Such information shall”  
19 and all that follows through the end of subpara-  
20 graph (B) and inserting “Such information  
21 shall, for each fiscal year, be submitted, up-  
22 dated, or reconfirmed on or before June 1 of  
23 the previous fiscal year.”; and

24 (4) in paragraph (2), as so redesignated—

1 (A) in the heading, by striking “CONTENTS  
2 OF NOTICE” and inserting “INFORMATION RE-  
3 QUIRED TO BE SUBMITTED”;

4 (B) in the matter preceding subparagraph  
5 (A), by striking “paragraph (2)” and inserting  
6 “paragraph (1)”;

7 (C) in subparagraph (A), by striking “or  
8 intended to be identified”;

9 (D) in subparagraph (D), by striking  
10 “and” at the end;

11 (E) in subparagraph (E), by striking the  
12 period and inserting “; and”; and

13 (F) by adding at the end the following:

14 “(F) whether the facility is a contract  
15 manufacturing organization facility.”.

16 (f) EFFECT OF FAILURE TO PAY FEES.—Section  
17 744B(g) of the Federal Food, Drug, and Cosmetic Act  
18 (21 U.S.C. 379–42(g)) is amended—

19 (1) in paragraph (1), by adding at the end the  
20 following: “This paragraph shall cease to be effective  
21 on October 1, 2022.”;

22 (2) in paragraph (2)(C)(ii), by striking “of  
23 505(j)(5)(A)” and inserting “of section  
24 505(j)(5)(A)”;

25 (3) by adding at the end the following:

1           “(5) GENERIC DRUG APPLICANT PROGRAM  
2       FEE.—

3           “(A) IN GENERAL.—A person who fails to  
4       pay a fee as required under subsection (a)(5) by  
5       the date that is 20 calendar days after the due  
6       date, as specified in subparagraph (D) of such  
7       subsection, shall be subject to the following:

8           “(i) The Secretary shall place the per-  
9       son on a publicly available arrears list.

10          “(ii) Any abbreviated new drug appli-  
11       cation submitted by the generic drug appli-  
12       cant or an affiliate of such applicant shall  
13       not be received, within the meaning of sec-  
14       tion 505(j)(5)(A).

15          “(iii) All drugs marketed pursuant to  
16       any abbreviated new drug application held  
17       by such applicant or an affiliate of such  
18       applicant shall be deemed misbranded  
19       under section 502(aa).

20          “(B) APPLICATION OF PENALTIES.—The  
21       penalties under subparagraph (A) shall apply  
22       until the fee required under subsection (a)(5) is  
23       paid.”.

24       (g) LIMITATIONS.—Section 744B(h)(2) of the Fed-  
25       eral Food, Drug, and Cosmetic Act (21 U.S.C. 379–

1 42(h)(2)) is amended by striking “for Type II active phar-  
2 maceutical ingredient drug master files, abbreviated new  
3 drug applications and prior approval supplements, and ge-  
4 neric drug facilities and active pharmaceutical ingredient  
5 facilities”.

6 (h) CREDITING AND AVAILABILITY OF FEES.—Sec-  
7 tion 744B(i) of the Federal Food, Drug, and Cosmetic Act  
8 (21 U.S.C. 379–42(i)) is amended—

9 (1) in paragraph (2)—

10 (A) by striking subparagraph (C) (relating  
11 to fee collection during first program year);

12 (B) in subparagraph (D)—

13 (i) in the heading, by striking “IN  
14 SUBSEQUENT YEARS”; and

15 (ii) by striking “(after fiscal year  
16 2013)”; and

17 (C) by redesignating subparagraph (D) as  
18 subparagraph (C); and

19 (2) in paragraph (3), by striking “fiscal years  
20 2013 through 2017” and inserting “fiscal years  
21 2018 through 2022”.

22 (i) INFORMATION ON ABBREVIATED NEW DRUG AP-  
23 PPLICATIONS OWNED BY APPLICANTS AND THEIR AFFILI-  
24 ATES.—Section 744B of the Federal Food, Drug, and



1 Cosmetic Act (21 U.S.C. 379–42) is amended by adding  
2 at the end the following:

3 “(o) INFORMATION ON ABBREVIATED NEW DRUG  
4 APPLICATIONS OWNED BY APPLICANTS AND THEIR AF-  
5 FILIATES.—

6 “(1) IN GENERAL.—By April 1 of each year,  
7 each person that owns an abbreviated new drug ap-  
8 plication, or any affiliate of such person, shall sub-  
9 mit, on behalf of the person and its affiliates, to the  
10 Secretary a list of—

11 “(A) all approved abbreviated new drug  
12 applications owned by such person; and

13 “(B) if any affiliate of such person also  
14 owns an abbreviated new drug application, all  
15 affiliates that own any such abbreviated new  
16 drug applications and all approved abbreviated  
17 new drug applications owned by any such affil-  
18 iate.

19 “(2) FORMAT AND METHOD.—The Secretary  
20 shall specify in guidance the format and method for  
21 submission of lists under this subsection.”.

22 **SEC. 304. REAUTHORIZATION; REPORTING REQUIREMENTS.**

23 Section 744C of the Federal Food, Drug, and Cos-  
24 metic Act (21 U.S.C. 379j–43) is amended—

25 (1) in subsection (a)—

1 (A) by striking “2013” and inserting  
2 “2018”; and

3 (B) by striking “Generic Drug User Fee  
4 Amendments of 2012” and inserting “Generic  
5 Drug User Fee Amendments of 2017”;

6 (2) in subsection (b), by striking “2013” and  
7 inserting “2018”; and

8 (3) in subsection (d), by striking “2017” each  
9 place it appears and inserting “2022”.

10 **SEC. 305. SUNSET DATES.**

11 (a) AUTHORIZATION.—Sections 744A and 744B of  
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13 379j–41; 379j–42) shall cease to be effective October 1,  
14 2022.

15 (b) REPORTING REQUIREMENTS.—Section 744C of  
16 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
17 379j–43) shall cease to be effective January 31, 2023.

18 (c) PREVIOUS SUNSET PROVISION.—Effective Octo-  
19 ber 1, 2017, subsections (a) and (b) of section 304 of the  
20 Food and Drug Administration Safety and Innovation Act  
21 (Public Law 112–144) are repealed.

22 **SEC. 306. EFFECTIVE DATE.**

23 The amendments made by this title shall take effect  
24 on October 1, 2017, or the date of the enactment of this  
25 Act, whichever is later, except that fees under part 7 of

1 subchapter C of chapter VII of the Federal Food, Drug,  
2 and Cosmetic Act shall be assessed for all abbreviated new  
3 drug applications received on or after October 1, 2017,  
4 regardless of the date of the enactment of this Act.

5 **SEC. 307. SAVINGS CLAUSE.**

6 Notwithstanding the amendments made by this title,  
7 part 7 of subchapter C of chapter VII of the Federal Food,  
8 Drug, and Cosmetic Act, as in effect on the day before  
9 the date of the enactment of this title, shall continue to  
10 be in effect with respect to abbreviated new drug applica-  
11 tions (as defined in such part as of such day) that on or  
12 after October 1, 2012, but before October 1, 2017, were  
13 received by the Food and Drug Administration within the  
14 meaning of 505(j)(5)(A) of such Act (21 U.S.C.  
15 355(j)(5)(A)), prior approval supplements that were sub-  
16 mitted, and drug master files for Type II active pharma-  
17 ceutical ingredients that were first referenced with respect  
18 to assessing and collecting any fee required by such part  
19 for a fiscal year prior to fiscal year 2018.

20 **TITLE IV—FEES RELATING TO**  
21 **BIOSIMILAR BIOLOGICAL**  
22 **PRODUCTS**

23 **SEC. 401. SHORT TITLE; FINDING.**

24 (a) SHORT TITLE.—This title may be cited as the  
25 “Biosimilar User Fee Amendments of 2017”.

(b) FINDING.—The Congress finds that the fees authorized by the amendments made in this title will be dedicated to expediting the process for the review of biosimilar biological product applications, including postmarket safety activities, as set forth in the goals identified for purposes of part 8 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate and the Chairman of the Committee on Energy and Commerce of the House of Representatives, as set forth in the Congressional Record.

**SEC. 402. DEFINITIONS.**

(a) ADJUSTMENT FACTOR.—Section 744G(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(1)) is amended to read as follows:

“(1) The term ‘adjustment factor’ applicable to a fiscal year is the Consumer Price Index for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All items; Annual Index) for October of the preceding fiscal year divided by such Index for October 2011.”.

(b) BIOSIMILAR BIOLOGICAL PRODUCT.—Section 744G(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–51(3)) is amended by striking “means

1 a product” and inserting “means a specific strength of  
2 a biological product in final dosage form”.

3 **SEC. 403. AUTHORITY TO ASSESS AND USE BIOSIMILAR**  
4 **FEES.**

5 (a) TYPES OF FEES.—Section 744H(a) of the Fed-  
6 eral Food, Drug, and Cosmetic Act (21 U.S.C. 379j–  
7 52(a)) is amended—

8 (1) in the matter preceding paragraph (1), by  
9 striking “fiscal year 2013” and inserting “fiscal year  
10 2018”;

11 (2) in the heading of paragraph (1), by striking  
12 “BIOSIMILAR” and inserting “BIOSIMILAR BIOLOGI-  
13 CAL PRODUCT”;

14 (3) in paragraph (1)(A)(i), by striking  
15 “(b)(1)(A)” and inserting “(c)(5)”;

16 (4) in paragraph (1)(B)(i), by striking  
17 “(b)(1)(B) for biosimilar biological product develop-  
18 ment” and inserting “(c)(5) for the biosimilar bio-  
19 logical product development program”;

20 (5) in paragraph (1)(B)(ii), by striking “annual  
21 biosimilar biological product development program  
22 fee” and inserting “annual biosimilar biological  
23 product development fee”;

24 (6) in paragraph (1)(B)(iii), by striking “an-  
25 nual biosimilar development program fee” and in-

1       serting “annual biosimilar biological product devel-  
2       opment fee”;

3               (7) in paragraph (1)(B), by adding at the end  
4       the following:

5                       “(iv) REFUND.—If a person submits a  
6                       marketing application for a biosimilar bio-  
7                       logical product before October 1 of a fiscal  
8                       year and such application is accepted for  
9                       filing on or after October 1 of such fiscal  
10                      year, the person may request a refund  
11                      equal to the annual biosimilar development  
12                      fee paid by the person for the product for  
13                      such fiscal year. To qualify for consider-  
14                      ation for a refund under this clause, a per-  
15                      son shall submit to the Secretary a written  
16                      request for such refund not later than 180  
17                      days after the marketing application is ac-  
18                      cepted for filing.”;

19               (8) in paragraph (1)(C), by striking “for a  
20       product effective October 1 of a fiscal year by,” and  
21       inserting “for a product, effective October 1 of a fis-  
22       cal year, by,”;

23               (9) in paragraph (1)(D)—

24                       (A) in clause (i) in the matter preceding  
25       subclause (I), by inserting “, if the person seeks

1 to resume participation in such program,” be-  
2 fore “pay a fee”;

3 (B) in clause (i)(I), by inserting after  
4 “grants a request” the following: “by such per-  
5 son”; and

6 (C) in clause (i)(II), by inserting after  
7 “discontinued)” the following: “by such per-  
8 son”;

9 (10) in the heading of paragraph (1)(E), by  
10 striking “BIOSIMILAR DEVELOPMENT PROGRAM”;

11 (11) in the heading of subparagraph (F) of  
12 paragraph (1), by striking “BIOSIMILAR DEVELOP-  
13 MENT PROGRAM FEES” and inserting “BIOSIMILAR  
14 BIOLOGICAL PRODUCT DEVELOPMENT FEES”;

15 (12) in paragraph (1)(F)—

16 (A) in the heading of subparagraph (F), by  
17 striking “BIOSIMILAR DEVELOPMENT PRO-  
18 GRAM” before “FEES”; and

19 (B) by amending clause (i) to read as fol-  
20 lows:

21 “(i) REFUNDS.—Except as provided  
22 in subparagraph (B)(iv), the Secretary  
23 shall not refund any initial or annual bio-  
24 similar biological product development fee  
25 paid under subparagraph (A) or (B), or

1           any reactivation fee paid under subpara-  
2           graph (D).”;

3           (13) in paragraph (2)—

4           (A) in the heading of paragraph (2), by  
5           striking “AND SUPPLEMENT”;

6           (B) by amending subparagraphs (A) and  
7           (B) to read as follows:

8           “(A) IN GENERAL.—Each person that sub-  
9           mits, on or after October 1, 2017, a biosimilar  
10          biological product application shall be subject to  
11          the following fees:

12               “(i) A fee established under sub-  
13               section (c)(5) for a biosimilar biological  
14               product application for which clinical data  
15               (other than comparative bioavailability  
16               studies) with respect to safety or effective-  
17               ness are required for approval.

18               “(ii) A fee established under sub-  
19               section (c)(5) for a biosimilar biological  
20               product application for which clinical data  
21               (other than comparative bioavailability  
22               studies) with respect to safety or effective-  
23               ness are not required for approval. Such  
24               fee shall be equal to half of the amount of  
25               the fee described in clause (i).



1           “(B) RULE OF APPLICABILITY; TREAT-  
2           MENT OF CERTAIN PREVIOUSLY PAID FEES.—  
3           Any person who pays a fee under subparagraph  
4           (A), (B), or (D) of paragraph (1) for a product  
5           before October 1, 2017, but submits a bio-  
6           similar biological product application for that  
7           product after such date, shall—

8                   “(i) be subject to any biosimilar bio-  
9                   logical product application fees that may  
10                  be assessed at the time when such bio-  
11                  similar biological product application is  
12                  submitted; and

13                  “(ii) be entitled to no reduction of  
14                  such application fees based on the amount  
15                  of fees paid for that product before Octo-  
16                  ber 1, 2017, under such subparagraph (A),  
17                  (B), or (D).”;

18                  (C) in the heading of subparagraph (D),  
19           by striking “OR SUPPLEMENT”; and

20                  (D) in subparagraphs (C) through (F)—

21                   (i) by striking “or supplement” each  
22                   place it appears; and

23                   (ii) in subparagraph (D), by striking  
24                   “or a supplement”; and

1           (14) by amending paragraph (3) to read as fol-  
2       lows:

3           “(3) BIOSIMILAR BIOLOGICAL PRODUCT PRO-  
4       GRAM FEE.—

5           “(A) IN GENERAL.—Each person who is  
6       named as the applicant in a biosimilar biologi-  
7       cal product application shall pay the annual bio-  
8       similar biological product program fee estab-  
9       lished for a fiscal year under subsection (c)(5)  
10      for each biosimilar biological product that—

11           “(i) is identified in such a biosimilar  
12      biological product application approved as  
13      of October 1 of such fiscal year; and

14           “(ii) as of October 1 of such fiscal  
15      year, does not appear on a list, developed  
16      and maintained by the Secretary, of dis-  
17      continued biosimilar biological products.

18           “(B) DUE DATE.—The biosimilar biologi-  
19      cal product program fee for a fiscal year shall  
20      be due on the later of—

21           “(i) the first business day on or after  
22      October 1 of each such year; or

23           “(ii) the first business day after the  
24      enactment of an appropriations Act pro-

1                   viding for the collection and obligation of  
2                   fees for such year under this section.

3                   “(C) ONE FEE PER PRODUCT PER YEAR.—

4                   The biosimilar biological product program fee  
5                   shall be paid only once for each product for  
6                   each fiscal year.

7                   “(D) LIMITATION.—A person who is  
8                   named as the applicant in a biosimilar biologi-  
9                   cal product application shall not be assessed  
10                  more than 5 biosimilar biological product pro-  
11                  gram fees for a fiscal year for biosimilar bio-  
12                  logical products identified in such biosimilar bi-  
13                  ological product application.”.

14                  (b) FEE REVENUE AMOUNTS.—Subsection (b) of sec-  
15                  tion 744H of the Federal Food, Drug, and Cosmetic Act  
16                  (21 U.S.C. 379j–52) is amended to read as follows:

17                  “(b) FEE REVENUE AMOUNTS.—

18                         “(1) FISCAL YEAR 2018.—For fiscal year 2018,  
19                         fees under subsection (a) shall be established to gen-  
20                         erate a total revenue amount equal to the sum of—

21                                 “(A) \$45,000,000; and

22                                 “(B) the dollar amount equal to the fiscal  
23                         year 2018 adjustment (as determined under  
24                         subsection (c)(4)).

1           “(2) SUBSEQUENT FISCAL YEARS.—For each of  
2           the fiscal years 2019 through 2022, fees under sub-  
3           section (a) shall, except as provided in subsection  
4           (c), be established to generate a total revenue  
5           amount equal to the sum of—

6                   “(A) the annual base revenue for the fiscal  
7                   year (as determined under paragraph (4));

8                   “(B) the dollar amount equal to the infla-  
9                   tion adjustment for the fiscal year (as deter-  
10                  mined under subsection (c)(1));

11                  “(C) the dollar amount equal to the capac-  
12                  ity planning adjustment for the fiscal year (as  
13                  determined under subsection (c)(2)); and

14                  “(D) the dollar amount equal to the oper-  
15                  ating reserve adjustment for the fiscal year, if  
16                  applicable (as determined under subsection  
17                  (c)(3)).

18           “(3) ALLOCATION OF REVENUE AMOUNT  
19           AMONG FEES; LIMITATIONS ON FEE AMOUNTS.—

20                   “(A) ALLOCATION.—The Secretary shall  
21                   determine the percentage of the total revenue  
22                   amount for a fiscal year to be derived from, re-  
23                   spectively—

1 “(i) initial and annual biosimilar de-  
2 velopment fees and reactivation fees under  
3 subsection (a)(1);

4 “(ii) biosimilar biological product ap-  
5 plication fees under subsection (a)(2); and

6 “(iii) biosimilar biological product pro-  
7 gram fees under subsection (a)(3).

8 “(B) LIMITATIONS ON FEE AMOUNTS.—  
9 Until the first fiscal year for which the capacity  
10 planning adjustment under subsection (c)(2) is  
11 effective, the amount of any fee under sub-  
12 section (a) for a fiscal year after fiscal year  
13 2018 shall not exceed 125 percent of the  
14 amount of such fee for fiscal year 2018.

15 “(C) BIOSIMILAR BIOLOGICAL PRODUCT  
16 DEVELOPMENT FEES.—The initial biosimilar bi-  
17 ological product development fee under sub-  
18 section (a)(1)(A) for a fiscal year shall be equal  
19 to the annual biosimilar biological product de-  
20 velopment fee under subsection (a)(1)(B) for  
21 that fiscal year.

22 “(D) REACTIVATION FEE.—The reactiva-  
23 tion fee under subsection (a)(1)(D) for a fiscal  
24 year shall be equal to twice the amount of the  
25 annual biosimilar biological product develop-

1           ment fee under subsection (a)(1)(B) for that  
2           fiscal year.

3           “(4) ANNUAL BASE REVENUE.—For purposes  
4           of paragraph (2), the dollar amount of the annual  
5           base revenue for a fiscal year shall be the dollar  
6           amount of the total revenue amount for the previous  
7           fiscal year, excluding any adjustments to such rev-  
8           enue amount under subsection (c)(3).”.

9           (c) ADJUSTMENTS; ANNUAL FEE SETTING.—Section  
10          744H of the Federal Food, Drug, and Cosmetic Act (21  
11          U.S.C. 379j–52) is amended—

12           (1) by redesignating subsections (c) through (h)  
13           as subsections (d) through (i), respectively;

14           (2) in subsections (a)(2)(F) and (g), by striking  
15           “subsection (c)” and inserting “subsection (d)”;

16           (3) in subsection (a)(4)(A), by striking “sub-  
17           section (b)(1)(F)” and inserting “subsection (c)(5)”;  
18           and

19           (4) by inserting after subsection (b) the fol-  
20           lowing:

21           “(c) ADJUSTMENTS; ANNUAL FEE SETTING.—

22           “(1) INFLATION ADJUSTMENT.—

23           “(A) IN GENERAL.—For purposes of sub-  
24           section (b)(2)(B), the dollar amount of the in-  
25           flation adjustment to the annual base revenue

1           for each fiscal year shall be equal to the prod-  
2           uct of—

3                   “(i) such annual base revenue for the  
4                   fiscal year under subsection (b); and

5                   “(ii) the inflation adjustment percent-  
6                   age under subparagraph (B).

7                   “(B) INFLATION ADJUSTMENT PERCENT-  
8           AGE.—The inflation adjustment percentage  
9           under this subparagraph for a fiscal year is  
10          equal to the sum of—

11                   “(i) the average annual percent  
12                   change in the cost, per full-time equivalent  
13                   position of the Food and Drug Administra-  
14                   tion, of all personnel compensation and  
15                   benefits paid with respect to such positions  
16                   for the first 3 years of the preceding 4 fis-  
17                   cal years, multiplied by the proportion of  
18                   personnel compensation and benefits costs  
19                   to total costs of the process for the review  
20                   of biosimilar biological product applications  
21                   (as defined in section 744G(13)) for the  
22                   first 3 years of the preceding 4 fiscal  
23                   years; and

24                   “(ii) the average annual percent  
25                   change that occurred in the Consumer

1 Price Index for urban consumers (Wash-  
2 ington-Baltimore, DC-MD-VA-WV; Not  
3 Seasonally Adjusted; All items; Annual  
4 Index) for the first 3 years of the pre-  
5 ceding 4 years of available data multiplied  
6 by the proportion of all costs other than  
7 personnel compensation and benefits costs  
8 to total costs of the process for the review  
9 of biosimilar biological product applications  
10 (as defined in section 744G(13)) for the  
11 first 3 years of the preceding 4 fiscal  
12 years.

13 “(2) CAPACITY PLANNING ADJUSTMENT.—

14 “(A) IN GENERAL.—Beginning with the  
15 fiscal year described in subparagraph  
16 (B)(ii)(II), the Secretary shall, in addition to  
17 the adjustment under paragraph (1), further in-  
18 crease the fee revenue and fees under this sec-  
19 tion for a fiscal year to reflect changes in the  
20 resource capacity needs of the Secretary for the  
21 process for the review of biosimilar biological  
22 product applications.

23 “(B) CAPACITY PLANNING METHOD-  
24 OLOGY.—



1                   “(i) DEVELOPMENT; EVALUATION  
2                   AND REPORT.—The Secretary shall obtain,  
3                   through a contract with an independent ac-  
4                   counting or consulting firm, a report evalu-  
5                   ating options and recommendations for a  
6                   new methodology to accurately assess  
7                   changes in the resource and capacity needs  
8                   of the process for the review of biosimilar  
9                   biological product applications. The capac-  
10                  ity planning methodological options and  
11                  recommendations presented in such report  
12                  shall utilize and be informed by personnel  
13                  time reporting data as an input. The re-  
14                  port shall be published for public comment  
15                  not later than September 30, 2020.

16               “(ii) ESTABLISHMENT AND IMPLE-  
17               MENTATION.—After review of the report  
18               described in clause (i) and receipt and re-  
19               view of public comments thereon, the Sec-  
20               retary shall establish a capacity planning  
21               methodology for purposes of this para-  
22               graph, which shall—

23                   “(I) incorporate such approaches  
24                   and attributes as the Secretary deter-  
25                   mines appropriate; and

1                   “(II) be effective beginning with  
2                   the first fiscal year for which fees are  
3                   set after such capacity planning meth-  
4                   odology is established.

5                   “(C) LIMITATION.—Under no cir-  
6                   cumstances shall an adjustment under this  
7                   paragraph result in fee revenue for a fiscal year  
8                   that is less than the sum of the amounts under  
9                   subsections (b)(2)(A) (the annual base revenue  
10                  for the fiscal year) and (b)(2)(B) (the dollar  
11                  amount of the inflation adjustment for the fis-  
12                  cal year).

13                  “(D) PUBLICATION IN FEDERAL REG-  
14                  ISTER.—The Secretary shall publish in the Fed-  
15                  eral Register notice under paragraph (5) the fee  
16                  revenue and fees resulting from the adjustment  
17                  and the methodologies under this paragraph.

18                  “(3) OPERATING RESERVE ADJUSTMENT.—

19                  “(A) INTERIM APPLICATION; FEE REDUC-  
20                  TION.—Until the first fiscal year for which the  
21                  capacity planning adjustment under paragraph  
22                  (2) is effective, the Secretary may, in addition  
23                  to the adjustment under paragraph (1), reduce  
24                  the fee revenue and fees under this section for  
25                  a fiscal year as the Secretary determines appro-

1           priate for long-term financial planning pur-  
2           poses.

3           “(B) GENERAL APPLICATION AND METH-  
4           ODOLOGY.—Beginning with the first fiscal year  
5           for which the capacity planning adjustment  
6           under paragraph (2) is effective, the Secretary  
7           may, in addition to the adjustments under  
8           paragraphs (1) and (2)—

9                   “(i) reduce the fee revenue and fees  
10                  under this section as the Secretary deter-  
11                  mines appropriate for long-term financial  
12                  planning purposes; or

13                  “(ii) increase the fee revenue and fees  
14                  under this section if such an adjustment is  
15                  necessary to provide for not more than 21  
16                  weeks of operating reserves of carryover  
17                  user fees for the process for the review of  
18                  biosimilar biological product applications.

19           “(C) FEDERAL REGISTER NOTICE.—If an  
20           adjustment under subparagraph (A) or (B) is  
21           made, the rationale for the amount of the in-  
22           crease or decrease (as applicable) in fee revenue  
23           and fees shall be contained in the annual Fed-  
24           eral Register notice under paragraph (5) estab-

1           lishing fee revenue and fees for the fiscal year  
2           involved.

3           “(4) FISCAL YEAR 2018 ADJUSTMENT.—

4                   “(A) IN GENERAL.—For fiscal year 2018,  
5           the Secretary shall adjust the fee revenue and  
6           fees under this section in such amount (if any)  
7           as needed to reflect an updated assessment of  
8           the workload for the process for the review of  
9           biosimilar biological product applications.

10                   “(B) METHODOLOGY.—The Secretary shall  
11           publish under paragraph (5) a description of  
12           the methodology used to calculate the fiscal  
13           year 2018 adjustment under this paragraph in  
14           the Federal Register notice establishing fee rev-  
15           enue and fees for fiscal year 2018.

16                   “(C) LIMITATION.—No adjustment under  
17           this paragraph shall result in an increase in fee  
18           revenue and fees under this section in excess of  
19           \$9,000,000.

20           “(5) ANNUAL FEE SETTING.—For fiscal year  
21           2018 and each subsequent fiscal year, the Secretary  
22           shall, not later than 60 days before the start of each  
23           such fiscal year—

24                   “(A) establish, for the fiscal year, initial  
25           and annual biosimilar biological product devel-

1           opment fees and reactivation fees under sub-  
2           section (a)(1), biosimilar biological product ap-  
3           plication fees under subsection (a)(2), and bio-  
4           similar biological product program fees under  
5           subsection (a)(3), based on the revenue  
6           amounts established under subsection (b) and  
7           the adjustments provided under this subsection;  
8           and

9                   “(B) publish such fee revenue and fees in  
10           the Federal Register.

11                   “(6) LIMIT.—The total amount of fees assessed  
12           for a fiscal year under this section may not exceed  
13           the total costs for such fiscal year for the resources  
14           allocated for the process for the review of biosimilar  
15           biological product applications.”.

16           (d) APPLICATION FEE WAIVER FOR SMALL BUSI-  
17   NESS.—Subsection (d)(1) of section 744H of the Federal  
18   Food, Drug, and Cosmetic Act (21 U.S.C. 379j–52), as  
19   redesignated by subsection (c)(1), is amended—

20                   (1) by striking subparagraph (B);

21                   (2) by striking “shall pay—” and all that fol-  
22           lows through “application fees” and inserting “shall  
23           pay application fees”; and

24                   (3) by striking “; and” at the end and inserting  
25           a period.

1 (e) EFFECT OF FAILURE TO PAY FEES.—Subsection  
2 (e) of section 744H of the Federal Food, Drug, and Cos-  
3 metic Act (21 U.S.C. 379j–52), as redesignated by sub-  
4 section (c)(1), is amended by striking “all fees” and in-  
5 serting “all such fees”.

6 (f) CREDITING AND AVAILABILITY OF FEES.—Sub-  
7 section (f) of section 744H of the Federal Food, Drug,  
8 and Cosmetic Act (21 U.S.C. 379j–52), as redesignated  
9 by subsection (c)(1), is amended—

10 (1) in paragraph (2)—

11 (A) by striking subparagraph (C) (relating  
12 to fee collection during first program year) and  
13 inserting the following:

14 “(C) COMPLIANCE.—The Secretary shall  
15 be considered to have met the requirements of  
16 subparagraph (B) in any fiscal year if the costs  
17 described in such subparagraph are not more  
18 than 15 percent below the level specified in  
19 such subparagraph.”; and

20 (B) in subparagraph (D)—

21 (i) in the heading, by striking “IN  
22 SUBSEQUENT YEARS”; and

23 (ii) by striking “(after fiscal year  
24 2013)”; and

1           (2) in paragraph (3), by striking “2013  
2       through 2017” and inserting “2018 through 2022”.

3 **SEC. 404. REAUTHORIZATION; REPORTING REQUIREMENTS.**

4       Section 744I of the Federal Food, Drug, and Cos-  
5       metic Act (21 U.S.C. 379j–53) is amended—

6           (1) in subsection (a)—

7               (A) by striking “2013” and inserting  
8       “2018”; and

9               (B) by striking “Biosimilar User Fee Act  
10       of 2012” and inserting “Biosimilar User Fee  
11       Amendments of 2017”;

12          (2) in subsection (b), by striking “2013” and  
13       inserting “2018”;

14          (3) by striking subsection (d);

15          (4) by redesignating subsection (e) as sub-  
16       section (d); and

17          (5) in subsection (d), as so redesignated, by  
18       striking “2017” each place it appears and inserting  
19       “2022”.

20 **SEC. 405. SUNSET DATES.**

21       (a) AUTHORIZATION.—Sections 744G and 744H of  
22       the Federal Food, Drug, and Cosmetic Act, as amended  
23       by section 403 of this Act, shall cease to be effective Octo-  
24       ber 1, 2022.

1 (b) REPORTING REQUIREMENTS.—Section 744I of  
2 the Federal Food, Drug, and Cosmetic Act, as amended  
3 by section 404 of this Act, shall cease to be effective Janu-  
4 ary 31, 2023.

5 (c) PREVIOUS SUNSET PROVISION.—

6 (1) IN GENERAL.—Effective October 1, 2017,  
7 section 404 of the Food and Drug Administration  
8 Safety and Innovation Act (Public Law 112–144) is  
9 repealed.

10 (2) CONFORMING AMENDMENT.—The Food and  
11 Drug Administration Safety and Innovation Act  
12 (Public Law 112–144) is amended in the table of  
13 contents in section 2 by striking the item relating to  
14 section 404.

15 **SEC. 406. EFFECTIVE DATE.**

16 The amendments made by this title shall take effect  
17 on October 1, 2017, or the date of the enactment of this  
18 Act, whichever is later, except that fees under part 8 of  
19 subchapter C of chapter VII of the Federal Food, Drug,  
20 and Cosmetic Act shall be assessed for all biosimilar bio-  
21 logical product applications received on or after October  
22 1, 2017, regardless of the date of the enactment of this  
23 Act.



1 **SEC. 407. SAVINGS CLAUSE.**

2       Notwithstanding the amendments made by this title,  
3 part 8 of subchapter C of chapter VII of the Federal Food,  
4 Drug, and Cosmetic Act, as in effect on the day before  
5 the date of the enactment of this title, shall continue to  
6 be in effect with respect to biosimilar biological product  
7 applications and supplements (as defined in such part as  
8 of such day) that were accepted by the Food and Drug  
9 Administration for filing on or after October 1, 2012, but  
10 before October 1, 2017, with respect to assessing and col-  
11 lecting any fee required by such part for a fiscal year prior  
12 to fiscal year 2018.

13 **TITLE V—REAUTHORIZATION OF**  
14 **OTHER PROGRAMS**

15 **SEC. 501. REAUTHORIZATION OF PROVISION RELATING TO**  
16 **EXCLUSIVITY OF CERTAIN DRUGS CON-**  
17 **TAINING SINGLE ENANTIOMERS.**

18       Section 505(u)(4) of the Federal Food, Drug, and  
19 Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by strik-  
20 ing “2017” and inserting “2022”.

21 **SEC. 502. REAUTHORIZATION OF PEDIATRIC HUMANI-**  
22 **TARIAN DEVICE EXCEPTIONS.**

23       Section 520(m)(6)(A)(iv) of the Federal Food, Drug,  
24 and Cosmetic Act (21 U.S.C. 360j(m)(6)(A)(iv)) is  
25 amended by striking “2017” and inserting “2022”.

1   **SEC. 503. REAUTHORIZATION OF THE CRITICAL PATH PUB-**  
2                   **LIC-PRIVATE PARTNERSHIPS.**

3           Section 566(f) of the Federal Food, Drug, and Cos-  
4   metic Act (21 U.S.C. 360bbb–5(f)) is amended by striking  
5   “2013 through 2017” and inserting “2018 through  
6   2022”.

7   **SEC. 504. REAUTHORIZATION OF PEDIATRIC DEVICE CON-**  
8                   **SORTIA.**

9           Section 305(e) of Pediatric Medical Device Safety  
10   and Improvement Act of 2007 (Public Law 110–85; 42  
11   U.S.C. 282 note) is amended by striking “2013 through  
12   2017” and inserting “2018 through 2022”.

13   **SEC. 505. REAUTHORIZATION OF ORPHAN GRANTS PRO-**  
14                   **GRAM.**

15           Section 5(c) of the Orphan Drug Act (21 U.S.C.  
16   360ee(c)) is amended by striking “2013 through 2017”  
17   and inserting “2018 through 2022”.

18   **SEC. 506. REAUTHORIZATION OF INSPECTION PROGRAM.**

19           Section 704(g)(11) of the Federal Food, Drug, and  
20   Cosmetic Act (21 U.S.C. 374(g)(11)) is amended by strik-  
21   ing “October 1, 2017” and inserting “October 1, 2022”.

22   **SEC. 507. REAUTHORIZATION OF PEDIATRIC STUDY OF**  
23                   **DRUGS.**

24           Section 409I(e)(1) of the Public Health Service Act  
25   (42 U.S.C. 284m(e)(1)) is amended by striking “2013  
26   through 2017” and inserting “2018 through 2022”.

## **TITLE VI—ADDITIONAL PROVISIONS**

### **SEC. 601. TECHNICAL CORRECTIONS.**

(a) Section 3075(a) of the 21st Century Cures Act (Public Law 114–255) is amended—

(1) in the matter preceding paragraph (1), by striking “as amended by section 2074” and inserting “as amended by section 3102”; and

(2) in paragraph (2), by striking “section 2074(1)(C)” and inserting “section 3102(1)(C)”.

(b) Section 506G(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356g(b)(1)(A)) is amended by striking “identity” and inserting “identify”.

(c) Section 505F(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g(b)) is amended by striking “randomized” and inserting “traditional”.

(d) Section 505F(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g(d)) is amended by striking “2” and inserting “3”.

(e) Effective as of the enactment of the 21st Century Cures Act (Public Law 114–255)—

(1) section 3051(a) of such Act is amended by striking “by inserting after section 515B” and inserting “by inserting after section 515A”; and

1           (2) section 515C of the Federal Food, Drug,  
2           and Cosmetic Act (21 U.S.C. 360e–3), as inserted  
3           by such section 3051(a), is redesignated as section  
4           515B.

5           (f) Section 515B(f)(2) of the Federal Food, Drug,  
6           and Cosmetic Act (21 U.S.C. 360e–3(f)(2)), as redesignig-  
7           nated by subsection (d)(2) of this section, is amended by  
8           striking “a proposed guidance” and inserting “a draft  
9           version of that guidance”.

10          (g) Section 513(b)(5)(D) of the Federal Food, Drug,  
11          and Cosmetic Act (21 U.S.C. 360c(b)(5)(D)) is amended  
12          by striking “medical device submissions” and inserting  
13          “medical devices that may be specifically the subject of  
14          a review by a classification panel”.

○